Claims

1. A method for the concentration of PrP^{Sc} or digestion products thereof, wherein a body fluid or fluidized organ is treated with solid phase material such as e.g. magnetic beads (MB) whereby at least part of said material or beads, respectively, carries a prion binding site.

2. The method of claim 1, wherein the prion binding site is a factor with prion binding activity (PrPB).

3. The method of claim 1, wherein the fluidized organ is homogenized tissue of central nervous system.

4. The method of claim 1, wherein the fluidized organ is homogenized brain tissue.

5. The method of claim 1, wherein the fluid is a fluid that has been digested by proteinase K (PK).

6. The method of claim 2, wherein the solid phase materials, e.g. MBs, carrying PrPB are prepared by coupling MBs with blood serum, or blood plasma.

7. The method of claim 1, wherein the solid phase materials, e.g. MBs, carrying PrPB are prepared by coupling solid phase material with serum or plasma fraction II of ammonium sulfate precipitation.

8. The method of claim 1, wherein the solid phase materials, e.g. MBs, carrying PrPB are prepared by coupling MBs with plasma fraction I of ammonium sulfate precipitation.

9. The method of claim 1, wherein the solid phase materials, e.g. MBs, carrying PrPB are prepared by coupling solid phase material with PrPBIp or PrPBIIp or PrPBIIs.

10. A method for the detection, and optionally quantification, of PrP^{Sc} or digestion products thereof, wherein PrP^{Sc} is first concentrated according to

one of claims 1 to 6 and then detected, and optionally compared with a standard.

11. The method of claim 10, wherein the detection is performed by Western blot analysis.

12. PrPBIIs which is a factor with prion binding activity in fraction II of ammonium sulfate precipitation of serum.

13. PrPBIIp which is a factor with prion binding activity in fraction II of ammonium sulfate precipitation of normal or fresh frozen plasma.

14. PrPBIp which is a factor with prion binding activity in fraction I of ammonium sulfate precipitation of plasma.

15. Solid phase material, such as MBs, carrying a PrPB.

16. A composition for the purification of body fluids and/or the sterilization of surgical or diagnostic tools comprising a PrPB, preferably coupled to a solid phase material.

17. A method for the sterilization of surgical or diagnostic tools wherein said tools are treated with a PrPB comprising composition, preferably a composition comprising PrPB coupled to a solid phase material.

18. A method for the concentration and/or isolation of PrPBs wherein serum or plasma is subjected to fractionated ammonium sulfate precipitation thus that at least one PrPB of interest is precipitated, preferably in only one fraction.

19. The method of claim 18, wherein the PrPB comprising fraction is further purified by further protein isolation methods.

20. A method for purification and/or removal of pathological prion protein from body fluids or fluidized organs, such as blood, urine, cerebrospinal fluid, brain tissue, lymph nodes, tonsils, or for the sterilization of surgical and/or diagnostic tools basing on the affinity of PrPB for the pathological prion protein.

21. A method for the purification of body fluids, e.g. blood units, wherein the fluid is treated with PrPBIp.

22. A therapy regimen based on the modulation of production of PrPB for preventing the spread of prions in the body.

23. The regimen of claim 19, wherein the PrPB is PrPBIp.

24. A test for the detection of pathological prion protein in body fluids or organs such as blood, urine, cerebrospinal fluid, brain tissue, lymph nodes, tonsils etc, that utilizes the specific binding properties of PrPB to pathological prion protein.

25. The test of claim 24 that is embodied as a microtiter plate format immunoassay, e.g. ELISA assay, an immunoprecipitation assay, a BIACORE assay, a immunocytochemical assay, a histoblot assay, etc.

26. A DNA sequence specific for biosynthesis of PrPB and/or an expression vector comprising same.

27. A method for purification of PrPB by using PrP^{27-30} as bait.

28. Monoclonal and polyclonal antibodies produced in animals, such as mice, rabbits, chicken, or other species, and directed against PrPB.

29. Single-chain Fv fragments and other types of fragments of antibodies produced in recombinant phages or in other recombinant systems, and directed against PrPB.

30. A test predictive of susceptibility to prion diseases based on polymorphisms of PrPB, or on variations in the strength and pattern of production of PrPB.

31. A transgenic animal, in particular mouse that overproduces PrPB in brain, lymph nodes, or other organs, to be used in a bioassay for prions.

32. A knockout animal, in particular a knockout mouse, which is devoid of PrPB, to be used in a bioassay for prions.

33. Production method of PrPB by expressing a DNA sequence specific for the biosynthesis of PrPB in a suitable host cell, such as bacteria, yeast, fungi, or eukaryotic cells, and by purification of PrPB from the aforementioned organisms.

34. Use of natural or synthetic PrPB as a medicament for therapeutical applications in humans and animals.

35. A vaccination of organisms with natural or synthetic PrPB, in particular PrPBIp.

36. A diagnostic assay for human and/or animal diseases resulting from abnormal production and/or metabolism of PrPB.